DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 9, 2015

Cardiogard Medical Ltd
% Sheila Hemeon-Heyer
President
Heyer Regulatory Solutions
125 Cherry Lane
Armherst, Massachusetts 01002

Re: K141465
Trade/Device Name: Cardiogard Emboli Protection Cannula
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, Or Tubing
Regulatory Class: Class II
Product Code: DWF
Dated: December 10, 2014
Received: December 11, 2014

Dear Sheila Hemeon-Heyer,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K141465

Device Name: CardioGard Emboli Protection Cannula

Indications for Use:

The CardioGard Emboli Protection Cannula combines the function of a standard arterial cannula with an added suction mechanism to capture debris that may result from cardiac surgery. The CardioGard Emboli Protection Cannula is intended for perfusion of the ascending aorta during short term (≤ 6 hours) cardiopulmonary bypass (CPB) procedures. The CardioGard suction lumen is intended for the removal of particulate emboli during surgical procedures that require CPB.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use_____** (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

A. Submitter:

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C. Date Prepared: January 9, 2015

D. Device Name and Classification Information:

Trade Name:	CardioGard Emboli Protection Cannula
Classification Name:	Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass
Product Code, CFR:	DWF, 21 CFR 870.4210
Review Panel:	Cardiovascular Devices
Class:	II

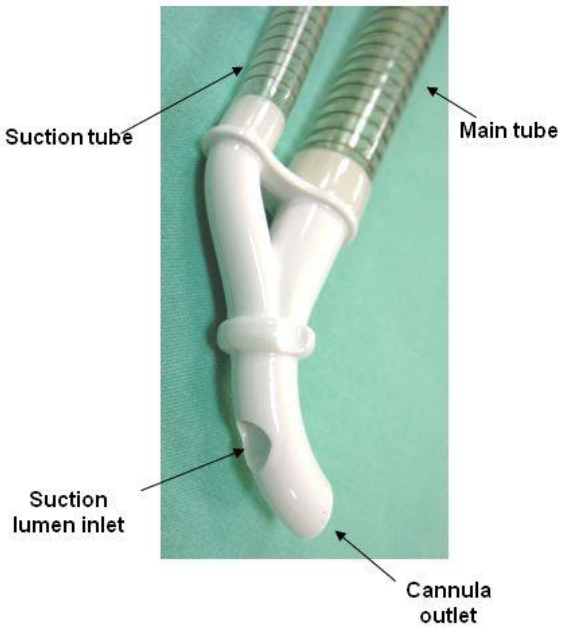
E. Predicate Device(s): Embol-X Access Device / Aortic Cannula, cleared under K102420 and K020693, and Embol-X Intra-Aortic Filter cleared under K062429, K031946, and K022071

F. Device Description:

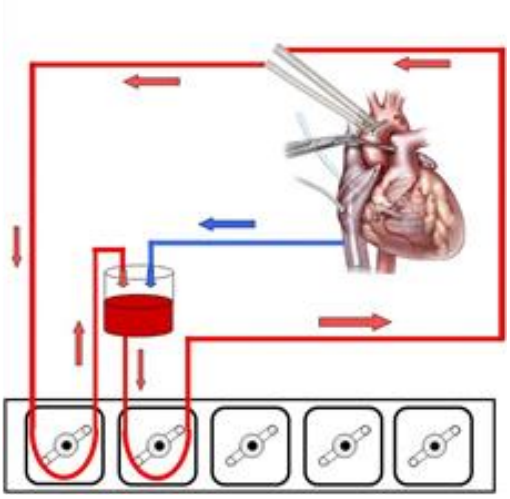
The CardioGard Emboli Protection Cannula, shown below, is a disposable 24 French double lumen arterial cannula. The cannula functions to deliver oxygenated blood to the heart during procedures requiring cardiopulmonary

bypass (CPB), while at the same time suctioning blood and embolic matter away from the surgical field. The arterial cannula is inserted centrally in the ascending aorta.

The CardioGard Emboli Protection Cannula features a tip configuration which diffuses oxygenated blood from the heart-lung machine to the ascending aorta through the Cannula Outlet, while also aspirating blood and embolic matter through the Suction Lumen Inlet. The flow rates through the two cannula lumens are carefully controlled so that emboli are suctioned back to the CPB machine for filtration while still enabling sufficient blood flow into the aorta.



CardioGard Features



CardioGard Inserted in the Heart-Lung Circuit

G. Indication for Use:

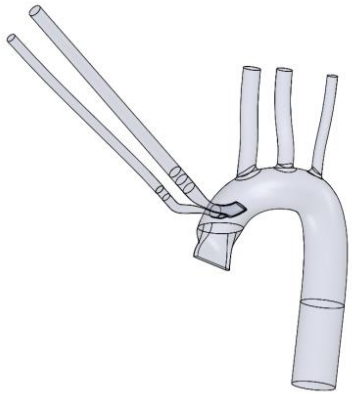
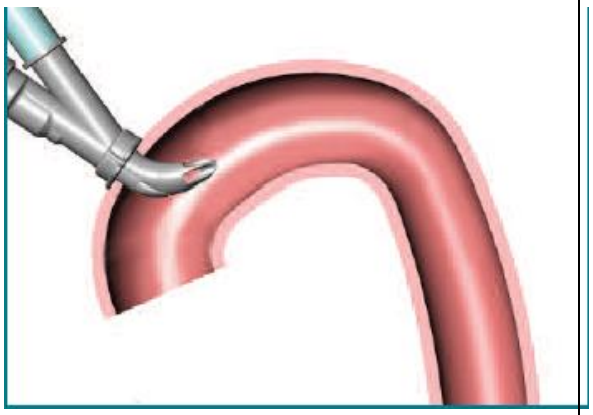
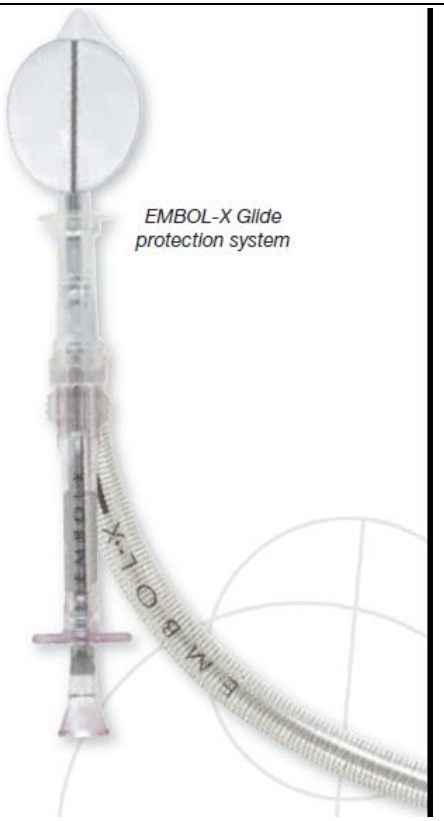
The CardioGard Emboli Protection Cannula combines the function of a standard arterial cannula with an added suction mechanism to capture debris that may result from cardiac surgery.

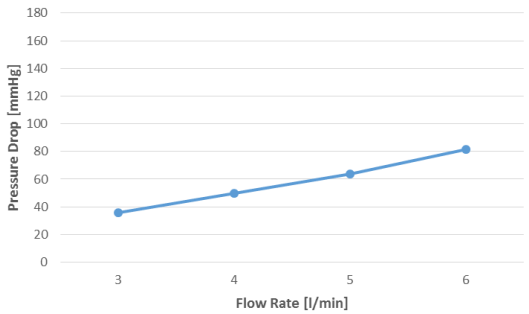
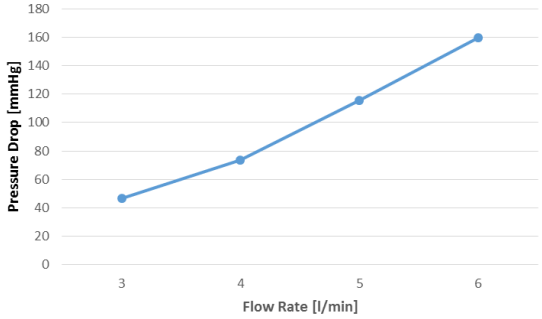
The CardioGard Emboli Protection Cannula is intended for perfusion of the ascending aorta during short term (≤ 6 hours) cardiopulmonary bypass (CPB) procedures. The CardioGard suction lumen is intended for the removal of particulate emboli during surgical procedures that require CPB.

H. Technical Comparison with Predicate Devices and Discussion of Similarities and Differences

Information for the predicate device was obtained from the 510(k) Summary and other publicly available sources.

	CardioGard Emboli Protection Cannula	**Embol-X Access Device / Aortic Cannula (K102420, K020693)**	**Embol-X Intra-Aortic Filter (K062429, K031946, K022071)**
Intended use	The CardioGard Emboli Protection Cannula combines the function of a standard arterial cannula with an added suction mechanism to capture debris that may result from cardiac surgery. The CardioGard Emboli Protection Cannula is intended for perfusion of the ascending aorta during short term (≤ 6 hours) cardiopulmonary bypass (CPB) procedures. The CardioGard suction lumen is intended for the removal of particulate emboli during surgical procedures that require CPB.	The EMBOL-X Access Device/Aortic Cannula is indicated for the perfusion of the ascending aorta during short-term (≤ 6 hours) cardiopulmonary bypass (CPB) surgery where procedures may require the hemostatic introduction and removal of compatible intravascular devices into the vascular system.	The Embol-X Intra-aortic filter is indicated for use with the Embol-X Access Device/Aortic Cannula in first time, non-emergent cardiac surgery procedures requiring aortic crossclamp, to capture and remove particulate emboli from the ascending aorta and heart in patients aged 18 years and older.
Use duration	For the length of the CPB surgery (≤ 6 hours)	For the length of the CPB surgery (≤ 6 hours)	The filter may remain *in situ* for up to 60 minutes.
Design	Two lumen, curved tip with two ports. One port is for aortic perfusion of oxygenated blood to the patient. The second port is for suction of embolic particles from the aortic arch.	Two lumen, curved tip with two ports. One port is for aortic perfusion of oxygenated blood to the patient. The second port is for insertion of the EMBOL-X filter device, intended to remove embolic particles from the aortic arch.	A cartridge that locks into the filter lumen of the EMBOL-X Cannula. The filter then opens to fill the diameter of the ascending aorta. The filter is intended to be inserted temporarily during CPB. Filters are manufactured in 5 sizes to conform to patient anatomy.

	CardioGard Emboli Protection Cannula	Embol-X Access Device / Aortic Cannula (K102420, K020693)	Embol-X Intra-Aortic Filter (K062429, K031946, K022071)
Dimensions	Tip Size: 24Fr Length: 30cm Main tube diameter: 3/8" Suction tube diameter: 1/4"	Tip Size: 24Fr; 20 Fr effective flow Length: 28 cm Main tube diameter: 3/8” Embolic filter port diameter: unknown	Five sizes available for aortas from 2.2 cm to 4.0 cm. Filter opens to fill the diameter of the ascending aorta.
Schematic of device			

	CardioGard Emboli Protection Cannula	Embol-X Access Device / Aortic Cannula (K102420, K020693)	Embol-X Intra-Aortic Filter (K062429, K031946, K022071)
Pressure Drop			N/A
Biological Safety	Tip material: PVC Tubing: PVC + Nirosta. Connector: ABS Biocompatibility has been confirmed in accordance with testing under ISO10993.	Polymeric tubes Biocompatible	Conventional medical grade materials and processes Biocompatible
Sterilization	EtO sterilized, single-use, disposable, non-pyrogenic	EtO sterilized, single-use, disposable, non-pyrogenic	Gamma radiation, single-use, disposable, non-pyrogenic

Discussion of Similarities and Differences

Intended Use: The intended use of the CardioGard Cannula is essentially the same as that of the combined Embol-X Aortic Cannula and Intra-Aortic filter. The Embol-X Intra-Aortic Filter can only be used with the Embol-X Aortic Cannula, and the two devices are sold together as the Embol-X Glide System. Both the CardioGard and Embol-X devices are intended for arterial perfusion and embolic particle capture during cardiopulmonary bypass (CPB) surgery.

Use Duration: The CardioGard Cannula is similar to the Embol-X Cannula in that both can be used for the entire duration of the CPB surgery (≤ 6 hours). The duration of use for the Embol-X filter is limited to 60 minutes, and it is intended primarily for use during periods of aortic manipulation (i.e., clamps removal).

Design and Dimensions: The designs of the CardioGard and Embol-X Cannulas are very similar. Both have curved tips with two ports: one for arterial perfusion and one for removal of embolic particles. Both devices are 24Fr with 3/8" diameter for the main tube, and similar tube lengths. Cannula insertion for both devices is per standard surgical practice for arterial perfusion cannulas. The main difference between the two device designs is the method of embolic particle removal: The CardioGard uses suction through the second portal located behind the perfusion portal, while the Embol-X uses a mesh filter inserted into the aorta through the second portal located behind the perfusion portal. In vitro side-by-side comparison testing of the two devices demonstrated the substantial equivalence of these two methods of embolic particle removal.

Pressure Drop:

The pressure drop (difference between the inlet and outlet pressures) testing was conducted for both the CardioGard and Embol-X cannulas under the same protocol. This in vitro side-by-side comparison pressure drop testing demonstrated that the CardioGard cannulas have a smaller, and therefore better, pressure drop as compared to the predicate device at all measured flow rates (3, 4, 5, and 6 l/min).

Biological Safety: The CardioGard Cannula is substantially equivalent to the Embol-X devices in that all are made of materials commonly used in medical devices and are biocompatible for short term contact with circulating blood.

Sterilization: The CardioGard Cannula is substantially equivalent to the Embol-X devices in that all are provided sterile, are non-pyrogenic, and are intended for single use only.

I. Nonclinical Data:

The following nonclinical testing was provided in this 510(k):

Sterilization Validation: EtO sterilization was validated to an SAL of 10^{-6} using the overkill method, half-cycle technique in accordance with EN ISO 11135-1:2008 Sterilization of health care products – Ethylene Oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices. The LAL test was used to verify that the EtO sterilized CardioGard is pyrogen-free.

Shelf Life Testing: Functionality and package integrity testing was conducted on finished, EtO sterilized devices after accelerated aging equivalent to 2 years. All tests passed, supporting a 2 year labelled shelf life. Functionality tests included:

- Visual Inspection and Dimensional Verification
- Back Pressure
- Pressure Drop
- Air Leakage
- Liquid Leakage
- Force at Break

Package tests included:

- Peel Strength (Tensile) Test
- Burst Test
- Dye Penetration Test

Biocompatibility Testing –Biocompatibility testing was conducted in accordance with ISO 10993-1:2009, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing," for externally communicating devices in contact with circulating blood for limited (<24 hours) duration. Tests included cytotoxicity, irritation, sensitization, acute systemic toxicity, mutagenicity/genotoxicity and hemocompatibility. All tests passed.

In Vitro Performance Testing: Comprehensive bench tests were conducted and are listed below. All tests passed the pre-defined acceptance criteria, where applicable.

- A series of numerical analyses to establish the device hemodynamic parameters
- In vitro testing in a silicone model of the aorta to establish the distribution profiles of embolic particles with the CardioGard used at different forward flow and backwards suction rates as compared to two commercially available aortic cannulas
- Mechanical performance testing for final design validation of device dimensions, back pressure, pressure drop, air leakage, liquid leakage, and force at break
- Side-by-side comparison testing of the CardioGard Cannula to the Embol-X Aortic Perfusion Cannula and Intra-Aortic Filter demonstrating:
    - Substantially lower pressure drop for CardioGard as compared to the Embol-X Cannula
    - Substantially equivalent back pressure for CardioGard as compared to the Embol-X Cannula
    - Substantially equivalent hemolysis potential for CardioGard as compared to the Embol-X Cannula and Filter when used in accordance with the instructions for use under test conditions simulating a 6 hour cardiopulmonary bypass procedure under worst case conditions (highest flow rates)
    - Substantially higher embolic particle capture for CardioGard as compared to the Embol-X Cannula and Filter when used in accordance with the instructions for use under test conditions simulating a 6 hour cardiopulmonary bypass procedure

Animal Testing: An acute animal study conducted in10 pigs (7 using the CardioGard Emboli Protection Cannula and 3 controls using a commercially available aortic perfusion cannula) demonstrated that the CardioGard device functioned well as an aortic perfusion cannula and captured a mean of 77% of injected osseous embolic particles when using the CardioGard Cannula suction feature at 1.0 or 1.5 L/min flow rates.

Clinical Testing: A prospective, randomized, multi-center, double-blind (subject and core-lab evaluators) clinical study was conducted to compare the safety and efficacy of the CardioGard Emboli Protection Cannula to

commercially available aortic perfusion cannulas during cardiac surgeries requiring cardiopulmonary bypass. The CardioGard device effectively removed measurable quantities of embolic particles throughout the surgery duration. Fewer CardioGard subjects exhibited new brain lesions following surgery, as evaluated by diffusion weighted magnetic resonance imaging (DW-MRI), compared to the subjects treated with the control cannulas (42.8% vs 66.7%, respectively), and this difference was statistically significant ($p<0.05$). Moreover, the average and total volume of new brain lesions were both significantly smaller for the CardioGard subjects as compared to Control ($p<0.05$). The CardioGard and Control groups were similar with regards to the type and incidence rates of adverse events and serious adverse events, most of which were isolated incidents and not unexpected during serious cardiac surgery requiring cardiopulmonary bypass.

I. Conclusion

The information and testing presented in this 510(k) demonstrates that the CardioGard Emboli Protection Cannula is substantially equivalent to the Embol-X Access Device / Aortic Cannula when used for aortic perfusion and when used together with the Embol-X Intra-aortic filter for removal of embolic particles during cardiopulmonary bypass surgery.